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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,081	08/06/2003	Pramod K. Gupta	24866A	9824

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WEYERHAEUSER COMPANY
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EXAMINER

PARA, ANNETTE H

ART UNIT	PAPER NUMBER
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1661

NOTIFICATION DATE	DELIVERY MODE
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11/14/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@weyerhaeuser.com

Office Action Summary

Application No.

10/636,081

Applicant(s)

GUPTA ET AL.

Examiner

Annette H. Para

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-19, 21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-19, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/2007 has been entered.

Listing of the Claims

Claims 1-13, 15-19, 21, 23 and 24 are examined. Claims 14, 20 and 22 have been cancelled.

Rejections - 35 U.S.C. 112 New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1-13, 15- 19,21,23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1 (a) applicants claim a maintenance medium comprising one or more agent for adjusting the osmolality of the medium to a desired range.

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The instant specification does not appear to provide support for a maintenance medium comprising one or more agents for adjusting the osmolality of the medium to a desired range. Examiner has reviewed page 2 to page 7, page 8, page 9, and pages 11 and Examples 1 and 2 (pages cited in applicants' response as support for the claim amendments) but did not find any support for this amendment. The specification only provides support for a maintenance medium; a maintenance medium comprising one or more agents for adjusting the osmolality of the medium to a desired range concentration is not supported.

Thus, such phrases constitute **NEW MATTER**. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

Claims 1-13, 15- 19,21,23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1 (c) applicants claim "incubating" the embryos.

The instant specification does not appear to provide support for incubating the embryos. On page 7 of the specification applicants teach that embryos can be cultured on a development medium for 9 to 14 weeks.

Incubating the embryos is not supported.

Thus, such phrases constitute **NEW MATTER**. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-18,21,23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in

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the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are very broad in the sense that the claims encompass a method for producing a synchronized population of conifer somatic embryos comprising the step of culturing conifer precotyledonary embryogenic cells in synchronization medium and then transferring them to a development medium.

The claim specifically broadly discloses conifer embryogenic cell, while the specification discloses only Douglas fir and Loblolly pine embryogenic cell. Applicant provides no guidance that would permit the skilled artisan to practice the invention. Applicant does not compare other types of conifer species in the specification, only Douglas fir and Loblolly pine. Additionally, as stated in claim 1, the word “comprising” is understood to be open-ended suggesting unknown components that are included in the procedure. The specification has provided very few working examples.

The state-of-the-art of Hansen *et al.* (“Recent advances in the transformation of plants,” Trends in Plant Science Reviews, June 1999, Vol. 4, No. 6, pages 226-231) teach that a tissue culture stage is required in most current transformation protocols to ultimately recover plants. Indeed, it is the totipotency plant cells that underlie most plant transformation systems (page 226, col. 2, paragraph 2). Embryogenic cells are, in general, very prolific and allow the recovery of many transformants that non-chimeric because of the assumed single cell origin of somatic embryos (page 227, at top of col. 1). Hansen *et al.* also teaches that plant transformation remains an art because of the unique culture conditions required for each crop species. To accommodate a genotype or species that has not been manipulated in culture previously, one must either adapt an established protocol, or created a new one, bearing in mind the efficiency imperatives (page 230, col. 2, paragraph 1).

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Applicants have shown a synchronized population of embryos for Douglas fir and loblolly pine through certain circumstance. However, there is not enough information in the specification that enables a method for producing a synchronized population of conifer somatic embryos. Thus, the disclosure does not provide enabling evidence for a person of ordinary skill in the art to determine without undue experimentation that this invention would work with any conifer embryogenic cell.

It is noted that there is not a single example in the instant specification, *working or prophetic*, which indicates that the product of the instant disclosure would be able to produce a synchronized population of embryos from all conifer species. For example, the data found in the specification is inconclusive to support the breadth of the claimed invention. Taking the examples into consideration, it appears that Applicant has used only Douglas fir and Loblolly pine in the experiments and they do have some effect on producing Douglas fir and Loblolly pine synchronized population of embryos from embryonic cell. However, there is no indication that this response can be reasonably extrapolated to include all conifer embryogenic cell; only Douglas fir and Loblolly pine are used in the examples.

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific procedures that achieve a method for producing conifer synchronized embryos. The specification does not provide such guidance and fails to provide evidence that all conifer synchronized embryos could be produced in this way. Without such guidance in the specification and the lack of correlative working examples, the claims would require an undue experimentation without a predictable degree of success on the part of the skilled artisan.

In re Fisher, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that “inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad

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enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.” (emphasis added).

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, claims 1-13, 15-18,21,23 and 24 are not considered fully enabled by the instant specification. There is no evidence to support these claims. Applicant is invited to provide page and line of the specification where evidence can be shown in the instantly claimed invention.

Considering the nature of the invention, the breadth of the claims, the unpredictable nature of the invention as recognized in the prior art, the lack of working examples and guidance provided, and the high degree of skill required to practice the invention, it is concluded that the specification does not provide an enabling disclosure for the instant claims. Therefore, additional experimentation is required before one of skill in the art could make and use the claimed invention. The amount of additional experimentation required to perform the broadly claimed invention is deemed to be undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 15-19, 21, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the term “adjusting the osmolality to a desired range” is not clear as to what is encompassed by “a desired range” How is this “desired range” measured? Clarification is needed.

Summary

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No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either the Private PAIR or the Public PAIR. Status information for unpublished applications is available through the Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov> . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Annette H Para/